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40. The method of claim 1 wherein the step of determining the presence of analyte in the urine test sample by viewing said first reaction site further comprises detecting the absence of analyte/chromogenic mobile specific binding partner complex at said first reaction site.

Clean Version of Each Replacement Claim

1. A method for determining the presence of Bence Jones Proteins in urine sample, comprising the steps of:

providing a conjugate pad comprising a chromogenic mobile specific binding partner for binding to analyte;

providing a chromatographic test strip comprising a matrix through which a urine test sample can flow by capillarity wherein said chromatographic test strip comprises at least two reaction sites;

a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of the analyte in the urine sample;

a control reaction site comprising a second immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner;

contacting said conjugate pad to said chromatographic test strip such that said first reaction site lies between said conjugate pad and said control reaction site;

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contacting said chromatographic test strip with an absorbent pad such that said absorbent pad is positioned opposite said conjugate pad and such that both said first reaction site and control reaction site lie in-between said conjugate pad and said absorbent pad;

developing said chromatographic test strip by applying urine sample suspected of containing said analyte thereto thereby allowing the same to contact said chromogenic mobile specific binding partner to form an analyte/chromogenic mobile

specific binding partner complex whereby capillarity carries the urine test sample along the strip to the first reaction site containing said first immobilized specific binding reagent and said control reaction site comprising said second immobilized specific binding partner;

determining the presence of analyte in the urine test sample by viewing said first reaction site;

determining if migration has occurred by detecting the presence of analyte/chromogenic mobile specific binding partner complex at said control reaction site; wherein detection may be made by observation of color at the control reaction site.

Q2 2. The method of claim 1 wherein the step of providing a chromatographic test strip further comprises providing a second reaction site positioned in-between said first reaction site and said control reaction site wherein said second reaction site is capable of immobilizing said chromogenic mobile specific binding partner in relation to the presence of said analyte in said urine, wherein said analyte is selected from the group consisting of free and bound kappa light chains, and free and bound lambda light chains.

3. The method of claim 1 wherein said analyte is selected from the group consisting of free and bound lambda light chains, free and bound kappa light chains, free kappa light chains, and free lambda light chains.

6. The method of claim 1 wherein said chromogenic mobile specific binding partner is selected from the group consisting of conjugated anti-free and bound kappa light chain antibody, and conjugated anti-free and bound lambda light chain antibody.

Q3 7. The method of claim 1 wherein said first immobilized specific binding reagent is selected from the group consisting of free and bound kappa light chains, free and bound lambda light chains, free kappa light chains, and free lambda light chains.

8. The method of claim 1 wherein said first immobilized specific binding reagent is selected from the group consisting of anti-free kappa light chain antibody, anti-free lambda light chain antibody, anti-free and bound kappa light chain antibody, and anti-free and bound lambda light chain antibody.

9. The method of claim 1 wherein said second immobilized specific binding reagent is Protein A.

10. The method of claim 1 further comprising providing a chromatographic test strip further comprising a second reaction site, wherein said second reaction site further comprises a third immobilized specific binding reagent selected from the group consisting of anti-free and bound kappa light chain antibody, anti free kappa light chain antibody, anti-free lambda light chain antibody, and anti-free and bound lambda light chain antibody.

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12. The method of claim 1 wherein the step of determining the presence of analyte in urine further comprises visualization of said first and said control reaction site, wherein the absence of band formation at said first reaction site indicates a positive result and the visualization of a band at said first reaction site indicates a negative result.

13. A device for the detection of analyte in urine comprising:

a conjugate pad said conjugate pad comprising a chromogenic mobile specific binding partner capable of binding to analytes;

a chromatographic test strip comprising a matrix through which urine can pass by capillarity carrying said mobile specific binding partner and said analyte, wherein said chromatographic test strip comprises three reaction sites,

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a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner bound to a first analyte in the urine sample,

a second reaction site comprising a second immobilizing specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner bound to second analyte in the urine sample,

a third control reaction site comprising a third immobilizing specific binding partner capable of immobilizing said mobile specific binding partner;

an absorbent pad disposed upon said chromatographic test strip such that said absorbent pad is positioned opposite said conjugate pad and such that said first reaction site, second reaction site, and said third reaction site lie in-between said conjugate pad and said absorbent pad.

15. The device of claim 13 wherein said first analyte is selected from the group consisting of free kappa light chains, free and bound kappa light chains, free lambda light chains, and free and bound lambda light chains.

20. The device of claim 13 wherein said chromogenic mobile specific binding partner is selected from the group consisting of conjugated anti-free and bound kappa light chain antibody, conjugated anti-free and bound lambda light chain antibody, conjugated anti-free kappa light chain antibody, and conjugated anti-free lambda light chain antibody.

21. The device of claim 13 wherein said first immobilized specific binding reagent is selected from the group consisting of anti-free kappa light chain antibody and anti-free lambda light chain antibody.

23. The device of claim 13 wherein said second immobilizing specific binding reagent is selected from the group consisting of anti-free and bound kappa light chain antibody,

Q6 and anti-free and bound lambda light chain antibody for the determination of the presence of whole antibody.

26. A test strip for the determination of an analyte in urine comprising:

a backing member;

a chromatographic test strip disposed upon said backing member said chromatographic test strip comprising a matrix through which a urine sample can flow by capillarity wherein said chromatographic test strip comprises at least two reaction sites,

a first reaction site comprising a first immobilized specific binding reagent capable of immobilizing a chromogenic mobile specific binding partner bound to said analyte in the urine sample; and

Q7 a second reaction site comprising a second immobilized specific binding reagent capable of immobilizing said chromogenic mobile specific binding partner; wherein said analyte is selected from the group consisting of free light chains and classes thereof.

28. The test strip of claim 26 wherein said chromogenic mobile specific binding partner is selected from the group consisting of anti-free kappa light chain antibody, anti-free and bound kappa light chain antibody, anti-free lambda light chain antibody, and anti-free and bound lambda light chain antibody.

29. The test strip of claim 26 wherein said first immobilized specific binding reagent is selected from the group consisting of free kappa light chains, free and bound kappa light chains, free lambda light chains, and free and bound lambda light chains.

Q8 30. The test strip of claim 26 wherein said second immobilized specific binding reagent is Protein A.
